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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/099,830	03/13/2002	Philip John Burke	ERD 100 CON	4061
23579	7590	07/23/2004	EXAMINER	
PATREA L. PABST PABST PATENT GROUP LLP 400 COLONY SQUARE SUITE 1200 ATLANTA, GA 30361			FETTEROLF, BRANDON J	
			ART UNIT	PAPER NUMBER
			1642	
DATE MAILED: 07/23/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/099,830

Applicant(s)

BURKE ET AL.

Examiner

Brandon J Fetterolf, PhD

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 05 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-45 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 34 and 41-45 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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Burke *et al.*

Date of Priority : 06/15/1998

## DETAILED ACTION

### *Election/Restrictions*

The response filed on May 5, 2004 to the restriction requirement of April 5, 2004 has been received. Claims 1-45 are pending in the application and Claims 1-33 and 35-40 have been canceled, without prejudice with the applicants understanding that these claims can be prosecuted in later filed applications. Claims 34 and 41, as amended, and new claims 42-45 are currently under consideration.

Applicant's election with traverse of Group 11, claim 34 and 41, as amended, and new claims 42-46 is acknowledged. The traversal is on the ground(s) that the parent application 09/445,865, now allowed, was subjected to a restriction requirement on February 13, 2001. The same claims are presented in this application, 10/099830 yet have been subjected to a different restriction requirement by the same examiner. For example, claims 13-17 were previously divided into three groups and now they are divided into two groups; claims 32 was previously placed into group 12; now it is placed into group 10 with a different set of claims. This is not found persuasive.

After reviewing the claim set from the parent application, the present examiner has found that terminology in the claim sets are different, some claims have been cancelled (claim 30) and new claims have been added (claim 41). Therefore, the restriction requirement is deemed to be proper and is therefore made FINAL.

Note: Newly added claims 41-46 appear to be mis-numbered as there is no Claim 43. Hence, the new claims have been re-numbered as Claims 41-45.

The original numbering of the claims must be preserved throughout the prosecution. When claims are canceled the remaining claims must not be renumbered. When claims are added, they must be numbered by the applicant consecutively beginning with the number next following the highest numbered claim previously presented (whether entered or not). See Rule § 1.126

Claims 1-45 are currently pending in this application.

Claims 34 and 41-45 are currently under consideration.

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*Priority*

A review of the United Kingdom application GB9712360.7 did not lend support for the disclosure for the compounds represented in formula 1. If applicant disagrees with any rejection of claims 34 and 41-45 set forth in this office action based on examiner's establishment of a priority date of **June 15, 1998** for the instant claims in application serial number 10/099830 applicant is invited to submit evidence pointing to the serial number, page and line where support can be found establishing an earlier priority date.

*Claim Rejections - 35 USC § 112*

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 34, and 41-45 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 34 and 41-45 are rejected as vague and indefinite for reciting "system" in claims 36 and 41-45. The term "system" is not defined by the claim, and the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

Claim 45 recites the limitation "analogue". There is insufficient antecedent basis for this limitation from which claim 45 depends.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 34, 41-45 are further rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a system comprising the prodrug CB 1945 which is converted to a substantially cytotoxic drug by the action of NQO2 and a compound of formula I, does not reasonably provide enablement for system as broadly claimed. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to practice the invention commensurate in scope with these claims.

The claims are drawn to a system comprising a prodrug which is converted to a substantially cytotoxic drug by the action of NQO2 and a compound of formula I, wherein the compound of formula 1 is 1-(carboxamidomethyl)-dihydronicotinamide (claims 41 and 45).

This includes any and all prodrugs.

However, one cannot extrapolate the teachings of the specification with the scope of the claims because the claims are drawn to a system comprising any and all prodrugs. The specification provides insufficient guidance and or objective evidence that all prodrugs would effectively be converted into cytotoxic drugs by the action of NQO2. Those of skill in the art of enzymology understand that it would be impossible for every known or potentially known prodrug to be an effective substrate for a particular enzyme especially when there are thousands of potential prodrugs which are not substrates for NQO2. Secondly, the specification provides insufficient guidance and or objective evidence of effective analogs of C81954 that would also effectively be converted into cytotoxic drugs by the action of NQO2. The specification only teaches that analogues of CB1954 are suitably defined as: molecules which retain the essential structural features of CB1954, i.e. a benzene ring containing an aziridine ring, two NO<sub>2</sub> groups and another substituent R but which differ in either the relative orientation of the substituents and/or in the nature of R (page 37, lines 19-28).

Thus, there are literally hundreds of possible analogs of CB1954, and it would be impossible to predict that any or all such analogs would effectively be converted into cytotoxic drugs by the action of NQO2. Reasonable correlation must exist between the scope of the claims and scope of enablement set forth, and it cannot be predicted from the disclosure that any and all analogs of C81954 or any all prodrugs would effectively be converted into a cytotoxic drug. Therefore, in view of the lack of predictability of the prior art, the breadth of the claims and the absence of working

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examples, it would require undue experimentation for one skilled in the art to practice the invention as claimed.

Therefore, NO claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brandon J Fetterolf, PhD whose telephone number is (571)-272-2919. The examiner can normally be reached Monday through Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeff Siew can be reached on (571) 272-0787. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brandon J Fetterolf, PhD  
Examiner  
Art Unit 1642

BF

  
**GARY NICKOL**  
**PRIMARY EXAMINER**